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\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Admitted only in Texas  
\*Practice Limited to  
Federal Agencies

January 22, 2003

**WRITER'S DIRECT NUMBER:**

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Commissioner for Patents  
Washington, D.C. 20231

*Hand Carry to Examiner A. Webhé  
Crystal Mall I, 7<sup>th</sup> Floor Reception  
Art Unit 1632*

Re: U.S. Utility Patent Application  
Appl. No. 09/937,604; U.S.C. § 371 Date: September 26, 2001  
For: **Adjuvant Compositions and Methods for Enhancing Immune  
Responses to Polynucleotide-Based Vaccines**  
Inventors: Wheeler, Carl J.  
Our Ref: 1530.0310002/EKS/EJH/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (14 sheets citing 56 documents);
3. 56 documents cited in Form PTO-1449 attached; and
4. One (1) return postcard.

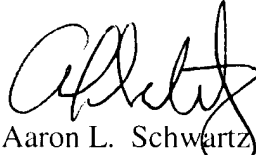
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
January 22, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Schwartz', is written over the printed name.

Aaron L. Schwartz  
Agent for Applicant  
Registration No. 48,181

EJH/ALS/lam  
Enclosures

::ODMA\MHODMA\SKGF\_DC1:92310:1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Wheeler, Carl J.

Appl. No. 09/937,604

U.S.C. § 371 Date: September 26, 2001

For: **Adjuvant Compositions and  
Methods for Enhancing  
Immune Responses to  
Polynucleotide-Based Vaccines**

Confirmation No. 2136

Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket: 1530.0310002/EKS/EJH/ALS

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**Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

United States Patent Application No. 09/580,463, Wheeler, Carl J., filed May 26, 2000, and submitted herewith as document AT11;

United States Patent Application No. 09/092,486, Wheeler, Carl J., filed June 5, 1998, and submitted herewith as document AR12;

United States Patent Application No. 09/557,907, Horton *et al.*, filed April 21, 2000, and submitted herewith as document AS12;

United States Patent Application No. 08/486,533, Felgner *et al.*, filed June 7, 1995, and submitted herewith as document AT12;

United States Patent Application No. 09/478,457, Wolff *et al.*, filed January 6, 2000,  
and submitted herewith as document AR13;

United States Patent Application No. 09/588,655, Wolff *et al.*, filed June 6, 2000,  
and submitted herewith as document AS13;

United States Patent Application No. 09/534,943, Wheeler, Carl J., filed March 24,  
2000, and submitted herewith as document AT13; and

United States Patent Application No. 10/127,683, Hobart *et al.*, filed April 23, 2002,  
and submitted herewith as document AR14.

United States Patent Application No. 10/202,858, Felgner *et al.*, filed July 26, 2002,  
and submitted herewith as document AS14.

The identification of these U.S. Patent Applications is not to be construed as a waiver  
of secrecy as to this application now or upon issuance of the present application as a patent.  
The Examiner is respectfully requested to consider the cited applications and the art cited  
therein during examination.

Where the publication date of a listed document does not provide a month of  
publication, the year of publication of the listed document is sufficiently earlier than the  
effective U.S. filing date and any foreign priority date so that the month of publication is not  
in issue. Applicants have listed publication dates on the attached PTO-1449 based on  
information presently available to the undersigned. However, the listed publication dates  
should not be construed as an admission that the information was actually published on the  
date indicated.

Applicants reserve the right to establish the patentability of the claimed invention  
over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

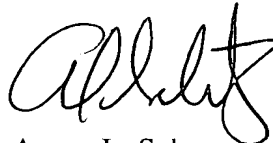
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Aaron L. Schwartz  
Agent for Applicant  
Registration No. 48,181

Date: January 22, 2003

1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
(202) 371-2600

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0310002/EKS/EJH/ALS	APPLICATION NO. 09/937,604
	APPLICANT Wheeler, Carl J.	
	U.S.C. § 371 DATE September 26, 2001	GROUP 2151

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,264,618	11/23/1993	Felgner et al.			04/16/1991
	AB1	5,334,761	08/02/1994	Gebeyehu et al.			08/28/1992
	AC1	5,459,127	10/17/1995	Felgner et al.			09/16/1993
	AD1	5,580,859	12/03/1996	Felgner et al.			03/18/1994
	AE1	5,589,466	12/31/1996	Felgner et al.			01/26/1995
	AF1	5,641,665	06/24/1997	Hobart et al.			11/28/1994
	AG1	5,676,954	10/14/1997	Brigham			05/08/1995
	AH1	5,693,622	12/02/1997	Wolff et al.			06/07/1995
	AI1	5,703,055	12/30/1997	Felgner et al.			01/26/1994
	AJ1	6,147,055	11/14/2000	Hobart et al.			03/14/1997
	AK1	6,235,310 B1	05/22/2001	Wang et al.			04/03/1998

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 94/29469	12/22/1994	WIPO			Yes No
	AM1	WO 97/19675	06/05/1997	WIPO			Yes No
	AN1	WO 00/57917	10/05/2000	WIPO			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>1</u>	Abbas, A.K. et al., "Functional diversity of helper T lymphocytes," <i>Nature</i> 383:787-793, Macmillan Journals Ltd. (1996).	
AS	<u>1</u>	Barnfield, C. et al., "The Cellular Basis of Immune Induction at Mucosal Surfaces by DNA Vaccination," <i>International Conference: Development and Clinical Progress of DNA Vaccines</i> , p. 28b (October 1999).	
AT	<u>1</u>	Barnfield, C. et al., "The Cellular Basis of Immune Induction at Mucosal Surfaces by DNA Vaccination," <i>Developments in Biological Standardization, Volume 104, Development and Clinical Progress of DNA Vaccines</i> , Brown, F., et al., eds., Basel, Karger, pp.159-164 (July 2000).	

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	6,399,588 B1	06/04/2002	Hobart et al.			07/28/2000
	AB						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	2	DeBruyne, L.A. et al., "Lipid-mediated gene transfer of viral IL-10 prolongs vascularized cardiac allograft survival by inhibiting donor-specific cellular and humoral immune responses," <i>Gene Ther.</i> 5:1079-1087 (August 1998).	
AS	2	Donnelly, J.J. et al., "Adjuvant Effects of DNA Vaccines," in <i>Vaccines 97</i> , Cold Spring Harbor Laboratory Press, pp. 105-111 (1997).	
AT	2	D'Souza, S. et al., "Improved Tuberculosis DNA Vaccines by Formulation in Cationic Lipids," <i>Infect. Immun.</i> 70:3681-3688, American Society for Microbiology (July 2002).	

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>3</u>	Etchart, N. et al., "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," <i>J. Gen. Virol.</i> 78:1577-1580, Society of General Microbiology (1997).	
AS	<u>3</u>	Felgner, P.L. et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417, The National Academy of Sciences of the United States of America (1987).	
AT	<u>3</u>	Felgner, J.H. et al., "Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations" <i>J. Biol. Chem.</i> 269:2550-2561, The American Society for Biochemistry and Molecular Biology, Inc. (1994).	

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>4</u>	Felgner, P.L., "Nonviral Strategies for Gene Therapy," <i>Sci. Am.</i> 276:102-106, Scientific American, Inc. (1997).	
AS	<u>4</u>	Fox, J.L., "No winners against AIDS," <i>Bio/Technology</i> 12:128, Nature Publishing Co. (1994).	
AT	<u>4</u>	Golding, B. et al., "The Potential for Recruiting Immune Responses Toward Type 1 or Type 2 T Cell Help," <i>Am. J. Trop. Med. Hyg.</i> 50:33-40, The American Society of Tropical Medicine and Hygiene (1994).	

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Gramzinski, R.A. et al., "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (February 1998).
	AS	<u>5</u>	Gregoriadis, G. et al., "Liposome-mediated DNA vaccination," <i>FEBS Lett.</i> 402:107-110, Elsevier Science B.V. (1997).
	AT	<u>5</u>	Ishii, N. et al., "Cationic Liposomes Are a Strong Adjuvant for a DNA Vaccine of Human Immunodeficiency Virus Type 1," <i>AIDS Res. Hum. Retroviruses</i> 13:1421-1428, Mary Ann Liebert, Inc. (1997).

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	AL						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>6</u>	Klavinskis, L.S. et al., "Mucosal immunization with DNA-liposome complexes," Vaccine 15:818-820, Elsevier Science Ltd. (1997).
	AS	<u>6</u>	Klavinskis, L.S. et al., "Intranasal Immunization with Plasmid DNA-Lipid Complexes Elicits Mucosal Immunity in the Female Genital and Rectal Tracts," J. Immunol. 162:254-262, American Association of Immunologists (January 1999).
	AT	<u>6</u>	"C <sub>35</sub> H <sub>71</sub> N <sub>2</sub> O <sub>2</sub> ," Chem. Abstracts 133(Formula Index):5164F, American Chemical Society (December 2000).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>7</u>	Norman, J.A. et al., "Development of improved vectors for DNA-based immunization and other gene therapy applications," Vaccine 15:801-803, Elsevier Science Ltd. (1997).
	AS	<u>7</u>	Norman, J. et al., "Adjuvants for Plasmid DNA Vaccines," in <i>Methods in Molecular Medicine</i> , Vol. 29, DNA Vaccines: Methods and Protocols, Lowrie, D.B. and R.G. Whalen, eds., Humana Press Inc., Totowa, NJ, pp. 185-196 (August 1999).
	AT	<u>7</u>	Okada, E. et al., "Intranasal Immunization of a DNA Vaccine with IL-12- and Granulocyte- Macrophage Colony-Stimulating Factor (GM-CSF)-Expressing Plasmids in Liposomes Induces Strong Mucosal and Cell-Mediated Immune Responses Against HIV-1 Antigens," <i>J. Immunol.</i> 159:3638-3647, American Association of Immunologists (1997).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>8</u>	Parker, S. et al., "Tissue Distribution of the Cytofectin Component of a Plasmid-DNA/Cationic Lipid Complex Following Intravenous Administration in Mice," <i>Hum. Gene Ther.</i> 8:393-401, Mary Ann Liebert, Inc. (1997).
	AS	<u>8</u>	Raz, E. et al., "Preferential induction of a Th <sub>1</sub> immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization," <i>Proc. Natl. Acad. Sci. USA</i> 93:5141-5145, The National Academy of Sciences of the United States of America (1996).
	AT	<u>8</u>	Sankar, V. et al., "Salivary gland delivery of pDNA-cationic lipoplexes elicits systemic immune responses," <i>Oral Dis.</i> 8:275-281, Blackwell Munksgaard (November 2002).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>9</u>	Stephan, D.J. et al., "A New Cationic Liposome DNA Complex Enhances the Efficiency of Arterial Gene Transfer In Vivo," <i>Hum. Gene Ther.</i> 7:1803-1812, Mary Ann Liebert, Inc. (1996).
	AS	<u>9</u>	Ulmer, J.B. et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," <i>Science</i> 259:1745-1749, American Association for the Advancement of Science (1993).
	AT	<u>9</u>	Wheeler, C.J. et al., "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. USA</i> 93:11454-11459, The National Academy of Sciences of the United States of America (1996).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>10</u>	Wheeler, C.J. et al., "Converting an alcohol to an amine in a cationic lipid dramatically alters the co-lipid requirement, cellular transfection activity and the ultrastructure of DNA-cytofectin complexes," <i>Biochimica et Biophysica Acta</i> 1280:1-11, Elsevier Science B.V. (1996).
	AS	<u>10</u>	Wheeler, C.J., "Adjuvant compositions and methods for enhancing immune responses to polynucleotide-based vaccines," <i>Chem. Abstracts</i> 133:636-637, Abs. No. 133:280556a, American Chemical Society (November 2000).
	AT	<u>10</u>	Yasutomi, Y. et al., "A Vaccine-Elicited, Single Viral Epitope-Specific Cytotoxic T Lymphocyte Response Does Not Protect against Intravenous, Cell-Free Simian Immunodeficiency Virus Challenge," <i>J. Virol.</i> 69:2279-2284, American Society for Microbiology (1995).

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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1530.0310002/EKS/EJH/ALS	APPLICATION NO. 09/937,604
	APPLICANT Wheeler, Carl J.	
	U.S.C. § 371 DATE September 26, 2001	GROUP 2151

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>11</u>	Yokoyama, M. et al., "DNA immunization: Effects of vehicle and route of administration on the induction of protective antiviral immunity," <i>FEMS Immunol. Med. Microbiol.</i> 14:221-230, Elsevier Science B.V. (1996).
	AS	<u>11</u>	International Search Report for International Patent Application No. PCT/US00/08282, mailed October 30, 2000.
	AT	<u>11</u>	Pending Non-Provisional United States Patent Application No. 09/580,463, Wheeler, Carl J., filed May 26, 2000 (NOT PUBLISHED).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>12</u>	Pending Non-Provisional United States Patent Application No. 09/092,486, Wheeler, Carl J., filed June 5, 1998 (NOT PUBLISHED).
	AS	<u>12</u>	Pending Non-Provisional United States Patent Application No. 09/557,907, Horton et al., filed April 21, 2000 (NOT PUBLISHED).
	AT	<u>12</u>	Allowed Non-Provisional United States Patent Application No. 08/486,533, Felgner et al., filed June 7, 1995 (NOT PUBLISHED).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>13</u>	Pending Non-Provisional United States Patent Application No. 09/478,457, Wolff et al., filed January 6, 2000 (NOT PUBLISHED).
	AS	<u>13</u>	Allowed Non-Provisional United States Patent Application No. 09/588,655, Wolff et al., filed June 6, 2000 (NOT PUBLISHED).
	AT	<u>13</u>	Allowed Non-Provisional United States Patent Application No. 09/534,943, Wheeler, Carl J., filed March 24, 2000 (NOT PUBLISHED).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>14</u>	Pending Non-Provisional United States Patent Application No. 10/127,683, Hobart et al., filed April 23, 2002 (NOT PUBLISHED).
	AS	<u>14</u>	Pending Non-Provisional United States Patent Application No. 10/202,858, Felgner et al., filed July 26, 2002 (NOT PUBLISHED).
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